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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,858	03/02/2005	Hiroyoshi Hidaka	8279.829USWO	5428
7590 01/12/2007 Hamre Schumann Mueller & Larson P. C. P.O. BOX Minneapolis, MN 55402			EXAMINER GEMBEH, SHIRLEY V	
			ART UNIT	PAPER NUMBER
			1614	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/12/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/526,858	<b>Applicant(s)</b> HIDAKA ET AL.	
	<b>Examiner</b> Shirley V. Gembeh	<b>Art Unit</b> 1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 October 2006.
- 2a) ☒ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4,9,15,16 and 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,9,15,16 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The response filed 10/18/06 presents remarks and arguments to the office action mailed 4/19/06. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' arguments, filed, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### **Status of Claims**

Claims 1-4,9, 15-16 and 27 are pending and examined.

Claims 1, 9 and 27 are amended.

Claims 5-8, 10-14, 17-26 are cancelled.

#### ***Claim Rejections - 35 USC § 103***

Claims 1-4,9, 15-16 and 27 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hidaka et al., US 5,972,976 in view of Goodman and Gilman, The Pharmacological Basis of therapeutics, and Ragaz et al., The new England J. of Med. (As in the office action of record).

Applicant argues that Hidaka fails to teach the compound with at least one of the antitumor agents cisplatin or carboplatin (see page 10 of remarks).

In response, the rejection is an obvious type, therefore the reference does not have to teach the combination, the Hidaka reference teaches the compound, and based on the knowledge of one of ordinary skill in the art, the compound is capable of being combined with the teaching of Goodman and Gilman. Next Adjuvant therapy is well known in the art, thus a motivation to combine. Cisplatin and carboplatin are drugs that are well known as antineoplastic agents as documented in Goodman and Gilman and have been used successful in adjuvant therapy, therefore nothing unobvious is seen in the combination of the compound of Hidaka and the teaching of Goodman and Gilman.

Next, Applicant argues that Table I of the specification compares the administration of the compound 2 alone and cisplatin alone with the survival rate of the combined effect.

In response, the Table I does not show the argument Applicant is trying to relay, for example, one set of data showed the compound administered together, while the other set showed administration on different days. With the example administration on the same day, no vast difference is seen with 2.5 of cisplatin and 25 of mg of compound 2. The same applies to the administration on different days. The only difference is the dosage increase of both the drugs when the cisplatin was administered (10 mg) first and the compound 2 (100 mg) was administered later the difference was greater than 500 T/C than when the compound was administered first and cisplatin administered later with the same dosage was 270 (T/C). Thus indicating that the the drug is not as

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effective as claimed and cast doubt on the effectiveness of the drug. Cisplatin in this case.

Applicant's arguments filed have been fully considered but they are not persuasive. See reasons above and the rejection is maintained.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembah whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG  
12/26/06

*Ardin H. Marschel 1/5/07*  
ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER